A Hard Pill to Swallow: A Critical Look at Eli Lilly & Co.'s NAFTA Challenge of the Canadian Patent Regime, and Its Potential Side Effects

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Abstract

On September 12, 2013, Eli Lilly & Co., in filing its Notice of Arbitration with the North American Free Trade Agreement against the Government of Canada, became the first private investor to contest a national patent regime through arbitral means. In the Notice, Lilly alleges that Canada violated NAFTA Articles 1110 (covering expropriation) and 1105 (covering minimum standards of treatment) by allowing Canada Federal Courts to unlawfully invalidate two of Lilly's patents, CA 2,041,113 and CA 2,209,735, protecting the compounds comprising Zyprexa and Strattera, respectively, through application of its controversial "promise doctrine." Whether arbitration through NAFTA is an appropriate way to contest a NAFTA member state's patent regime is hotly contested. But Canada Federal Courts have invalidated an increasing number of pharmaceutical patents for failing to meet the promise doctrine, leaving pharmaceutical companies in Canada uncertain as to the extent of their patent rights. Still, NAFTA allowing pharmaceutical companies to successfully dispute national patent laws could have significant future consequences. This note outlines the circumstances surrounding Lilly's dispute, analyzes the dispute's viability, and explores various potential implications of the dispute going forward.

I. Introduction

On September 12, 2013, Eli Lilly & Company (Lilly) shocked the legal world when it filed a "Notice of Arbitration" (Notice) under Chapter 11 of the North American Free Trade Agreement (NAFTA) against the Government of Canada (Canada) for permitting its courts to apply certain patent restrictions in particular ways.[1] For the first time ever, a

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1. *See generally* Eli Lilly & Co. v. Canada, Notice of Arbitration, In the Arbitration under the Arbitration Rules of the United Nations Commission on International Trade Law and the North American Free Trade

trade agreement is being used as a means to challenge aspects of a national patent regime.[2] In the arbitration notice, Lilly seeks CND $500 million in damages from Canada for allowing its courts to misapply the "doctrine of sound prediction" (also known as the "promise doctrine").[3] Lilly filed the arbitration notice in response to the Canada Federal Court of Appeal (the Court of Appeal) retroactively invalidating two patents, CA 2,041,113 (the '113 patent) and CA 2,209,735 (the '735 patent) (collectively, the Lilly patents), which safeguarded Lilly's privilege in Canada to the compounds comprising Zyprexa and Strattera, respectively.[4]

Whether arbitration under NAFTA is an appropriate way to contest a member state's (Party's) patent regime is a hotly contested issue.[5] But Canada has a growing number of pharmaceutical patents being invalidated for failing to meet the promise doctrine,[6] leaving pharmaceutical companies uncertain as to the scope of their patent rights.[7] Accordingly, recourse should arguably be available for pharmaceutical companies under similar circumstances.[8] Yet, allowing pharmaceutical companies to seek remedy under NAFTA from national patent laws could have significant implications going forward.[9]

This note will outline the circumstances surrounding Lilly's decision to pursue Chapter 11 arbitration and analyze the dispute's viability. Additionally, this note will explore potential future consequences of Lilly's arbitration filing. Part II of this note will explain the law and facts leading up to, and surrounding, Lilly's arbitration notice. Part III will analyze whether Lilly's Chapter 11 claims, specifically under Articles 1110 and 1105, are legally viable and will conclude that they likely are. Lastly, Part IV will discuss potential implications of Lilly's challenge going forward, even in the absence of a favorable verdict for Lilly.

Agreement (Sept. 12, 2013) *available at* http://www.international.gc.ca/trade-agreements-accords-commerciaux/assets/pdfs/disp-diff/eli-03.pdf [hereinafter Notice of Arbitration].

2. *See* Latha Jishnu, *A Treaty Too Many*, DOWN TO EARTH, May 15, 2013, *available at* http://www.downtoearth.org.in/content/treaty-too-many ("Eli Lilly . . . issued a notice of intent to challenge Canada's patent policy under . . . NAFTA. Such arbitration is likely to open a Pandora's box. So far patent policies have not come under the investor-state mechanism . . . .").

3. *See* Notice of Arbitration, *supra* note 1, ¶¶ 72, 85(i).

4. *See id.* ¶ 21; *see also* Eli Lilly Can. Inc. v. Novopharm Ltd., [2012] F.C.A. 232 (Can.); *see also* Eli Lilly & Co. v. Teva Can. Ltd., [2011] F.C.A. 220 (Can.).

5. *See, e.g., Eli Lilly Files for NAFTA Arbitration in $500M Drug Patent Dispute with Ottawa*, CAN. PRESS (Sept. 13, 2013, 4:53 PM), *available at* http://www.ctvnews.ca/business/eli-lilly-files-for-nafta-arbitration-in-500m-drug-patent-dispute-with-ottawa-1.1454069 ("The [Lilly] challenge comes amid ongoing debate regarding investor protection rights in Canada's trade agreements . . . .").

6. *See, e.g.*, Notice of Arbitration, *supra* note 1, ¶ 11 ("Since the advent of the promise doctrine, 18 pharmaceutical patents have been invalidated for lack of utility in Canada. In the prior 25 years, only two patents were invalidated for lack of utility . . . .").

7. *See id.* ¶¶ 11, 12 ("[E]very patent invalidated since 2005 for lack of utility has been a pharmaceutical invention. Canada's adoption of the promise doctrine was a watershed event in the development of Canada's intellectual property regime.").

8. *See id.* ¶ 12 ("Not only is Canada applying a utility test that violates the standard required under NAFTA, it is also applying the utility test in a way that discriminates against pharmaceuticals as a field of technology. This itself contravenes Canada's obligation under NAFTA Article 1709(7) to make patents available and patent rights enjoyable without discrimination.").

9. *See* Jishnu, *supra* note 2.

II. Background

Lilly, founded by a Civil War veteran in 1876,[10] has grown into the tenth-largest pharmaceutical company in the world.[11] It is a leader in research and development for psychiatric and mental-health medicines,[12] having brought to market some of the highest grossing drugs of all time.[13] Although its greatest presence is in the United States,[14] Lilly develops, manufactures, markets, and sells medicines across the globe.[15] Like other major pharmaceutical conglomerates, Lilly faces significant economic burdens from various sources, like pro-generic legislation[16] and industry-wide regulation.[17] Even product development costs stagger; every new drug brought to market sets companies back an average of USD $5 billion.[18] In a country without sufficiently "protective" laws, drug developers like Lilly would have no choice but to avoid the risks of innovation and slow or halt development altogether. So, Lilly depends on intellectual property rights—the "lifeblood . . . for innovation"[19]—to generate "sufficient financial incentives to pursue R&D" of enhanced medicines.[20]

Zyprexa and Strattera, used for schizophrenia treatment and attention-deficit hyperactivity disorder (ADHD), respectively, are two of Lilly's medicines that it would likely describe as "enhanced."[21] Zyprexa, which is an olanzapine compound, was protected by the

10. *See, e.g.*, James H. Madison, *Manufacturing Pharmaceuticals: Eli Lilly and Company, 1876-1948*, 18 BUS. & ECON. HISTORY 72, 72 (1989), *available at* http://www.thebhc.org/publications/BEHprint/v018/p0072-p0078.pdf.

11. *See Sensory Technologies Designs & Integrates Immersive Collaborative Experiences for Eli Lilly*, PROF. SYS. NETWORK INT'L, http://www.psni.org/project/sensory-technologies-designs-integrates-immersive-collaborative-experiences-for-eli-lilly/ (last visited Feb. 5, 2014).

12. *See, e.g.*, Thomas M. Burton, *Eli Lilly Leveraging Prozac Success into New Drug Developments*, SCHIZOPHRENIA.COM, http://www.schizophrenia.com/news/elilily.html (last visited Feb. 5, 2014) ("Eli Lilly & Co. shot to the forefront of psychiatric therapy . . . .").

13. *See, e.g.*, Bethany McLean, *A Bitter Pill Prozac Made Eli Lilly. Then Along Came a Feisty Generic Maker Called Barr Labs. Their Battle Gives New Meaning to the Term 'Drug War.'*, FORTUNE, Aug. 13, 2001, at 118, *available at* http://money.cnn.com/magazines/fortune/fortune_archive/2001/08/13/308077/.

14. *See, e.g.*, *Key Facts*, LILLY, http://www.lilly.com/about/key-facts/Pages/key-facts.aspx (last visited Feb. 5, 2014) (comparing the number of Lilly employees worldwide [38,000] to the number of Lilly employees exclusively outside of the United States [21, 437]).

15. *See generally id.*

16. *See, e.g.*, The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271), as amended by the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (also known as the Hatch-Waxman Act).

17. *See, e.g.*, *Drugs and Health Products, Drug Products*, HEALTH CAN., http://www.hc-sc.gc.ca/dhp-mps/prodpharma/index-eng.php (last visited Feb. 5, 2014) ("Before drug products are authorized for sale in Canada, Health Canada reviews them to assess their safety, efficacy and quality. Drug products include prescription . . . pharmaceuticals . . . .").

18. *See* Matthew Herper, *The Cost of Creating A New Drug Now $5 Billion, Pushing Big Pharma to Change*, FORBES (Aug. 11, 2013, 11:10 AM), http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/.

19. Notice of Arbitration, *supra* note 1, ¶ 2.

20. Thomas Cheng, *Putting Innovation Incentives Back in the Patent-Antitrust Interface*, 11 NW J. TECH. & INTELL. PROP. 385, 387 (2013), *available at* http://scholarlycommons.law.northwestern.edu/cgi/viewcontent.cgi?article=1195&context=njtip.

21. *See* Notice of Arbitration, *supra* note 1, ¶¶ 26–27.

'113 patent, a secondary patent that issued in 1998.[22] Regarding the '113 patent, Lilly claimed that the disclosed compound had "surprising and excellent results,"[23] "marked superiority, and a better side effects profile than prior known antipsychotic agents."[24] Strattera, which is atomoxetine, was protected by the '735 patent.[25] The '735 patent disclosed using atomoxetine for ADHD treatment, contrasted with its use as an anti-depressant.[26] Lilly demonstrated that "atomoxetine could be use[ful] in the treatment of ADHD" with results from an internal 22-patient study.[27]

Roughly twenty years after grant of the Lilly patents, Zyprexa and Strattera are prescribed to hundreds of thousands of Canadians and net billions of dollars in annual sales worldwide.[28] Zyprexa, referred to by Lilly as its "breakthrough product for schizophrenia and bipolar mania,"[29] landed its inventors the prestigious "PhRMA Discoverers Award" in 2000[30] and amounted to 22 percent of Lilly's revenues in 2010.[31] In a similar fashion, Strattera has made waves as "the first nonstimulant, noncontrolled drug approved for attention-deficit hyperactivity disorder" in all age groups.[32] Still, the Court of Appeal ultimately invalidated the Lilly patents after finding that their respective medicines lacked utility under the Canada Patent Act (the Patent Act).[33]

A. The Patent Act's Utility Requirements and the Promise Doctrine

The Patent Act empowers the owner of a patent for an invention with "the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used."[34] Similarly to other national patent systems, the Patent Act establishes a framework that limits patent grants to useful, novel, and non-obvious inventions, exclusively.[35] Specifically, Section 2 of the Patent Act defines "invention" as "any new and *useful art, process, machine, manufacture or composition of matter*, or any new and *useful im-*

22. *See* CA Patent No. 2,041,113 (filed Apr. 24, 1991).

23. *Id.* at 4.

24. *Id.* at 6.

25. *See* CA Patent No. 2,209,735 (filed Apr. 24, 1991).

26. *See id.*

27. Notice of Arbitration, *supra* note 1, ¶¶ 49–50.

28. *See id.* ¶¶ 26 – 27.

29. *Lilly Announces Fourth-Quarter Earnings Per Share of $.60, Excluding One-Time Charges*, Lilly, https://investor.lilly.com/releasedetail2.cfm?releaseid=70219 (last visited Feb. 5, 2014).

30. *See, e.g.*, *Discoverers Awards*, Innovation, http://www.innovation.org/index.cfm/StoriesofInnovation/InnovatorStories/Discoverers_Awards (last visited Feb. 5, 2014).

31. *See, e.g.*, Tom Randall & Elizabeth Lopatto, *Lilly Reports Profit Higher Than Analysts Estimated, Misses on Forecast*, Bloomberg (Jan. 27, 2011, 8:54 AM), http://www.bloomberg.com/news/2011-01-27/lilly-fourth-quarter-profit-increases-more-than-analysts-estimated.html.

32. Ruth Woodrow, Bruce Colbert & David M. Smith, Essentials of Pharmacology for Health Occupations 352 (6th ed. 2011) (emphasis omitted).

33. *See* Eli Lilly Can. Inc. v. Novopharm Ltd., [2012] F.C.A. 232 (Can.); *see also* Eli Lilly & Co. v. Teva Can. Ltd., [2011] F.C.A. 220 (Can.).

34. Canada Patent Act, R.S.C. 1985, c. P-4, § 42, *available at* http://laws-lois.justice.gc.ca/PDF/P-4.pdf [hereinafter Patent Act].

35. *See id.* § 28.3.

provement [thereof]."[36] Hence, utility is indispensable for obtaining and maintaining a patent in Canada.[37]

The current requirements for utility, largely promulgated by the Supreme Court of Canada (the Supreme Court), set out that an invention possesses utility only if "when used in accordance with the directions contained in the specification the *promised results* are obtained."[38] Whether promised results are obtained is a question of fact and must be shown by "either demonstration or *sound prediction based on the information and expertise then available*."[39] Moreover, a sound prediction exists only when there is (1) "a factual basis for the prediction"; (2) "an articulable and 'sound' line of reasoning from which the desired result can be inferred from the factual basis" upon filing; and (3) "proper disclosure."[40] These judge-propounded conditions for invention utility comprise the promise doctrine.[41]

Pharmaceutical companies have a particularly difficult time satisfying the promise doctrine's requirements because of the Phase II human testing that medicines must undergo for federal approval.[42] Some argue that requiring the promise doctrine to be met for utility, in addition to fulfilling the statutory patent novelty, creates a "catch-22."[43] Specifically, to soundly predict that a medicine's promises are sufficiently accurate, it must be subject to Phase II trials, which require public disclosure that will likely result in a statutory bar against novelty.[44] Ironically, the promise doctrine originated "to allow inventors to expand claims to cover a class of compounds or processes that had not all been tested."[45] Since its gestation, however, it has evolved into a pharmaceutical patent invalidation tool in Canada—and the basis for Lilly's NAFTA dispute against Canadian sovereignty.[46]

B. Litigation of the '113 Patent

Lilly sued Novopharm Limited (Novopharm) for patent infringement of the '113 patent, which in turn contested the '113 patent's validity.[47] On October 5, 2009, the Canada Federal Court (the Trial Court) nonsuited Lilly's patent infringement claims against

36. *Id.* § 2 (emphasis added).

37. *See generally id.*

38. Consolboard, Inc. v. MacMillan Bloedel (Sask.), Ltd., [1981] 1 S.C.R. 504, 526 (Can.) (emphasis added).

39. Apotex, Inc. v. Wellcome Found. Ltd., [2002] 4 S.C.R. 153, 155 (Can.) (emphasis added).

40. *Id.*

41. *See id.*

42. *See, e.g.*, John Lechleiter, *How Lax Patent Rules In Canada Are Suffocating Life-Saving Innovation*, Forbes (Aug. 26, 2013, 9:00 AM), http://www.forbes.com/sites/johnlechleiter/2013/08/26/how-lax-patent-rules-in-canada-are-suffocating-life-saving-innovation/.

43. *See, e.g., id.*

44. *See, e.g.*, Douglas K. Norman, *Opportunities and Challenges in the Search for New Medicines*, Pharmaphorum (Sept. 25, 2013), http://www.pharmaphorum.com/articles/opportunities-and-challenges-in-the-search-for-new-medicines.

45. Brian R. Daley, *Does the Doctrine of Sound Prediction Make it Harder for Inventive People to Obtain Patents in Canada?*, 27 Can. Intell. Prop. Rev. 363, 363 (Dec. 2011), *available at* http://www.nortonrosefulbright.com/files/does-the-doctrine-of-sound-prediction-make-it-harder-for-inventive-people-to-obtain-patents-in-canada-pdf-220kb-64162.pdf.

46. *See generally* Notice of Arbitration, *supra* note 1.

47. Eli Lilly Can. Inc. v. Novopharm Ltd., [2009] F.C. 1018, ¶ 1 (Can.).

Novopharm in finding that the '113 patent was invalid as a selection patent.[48] The Court of Appeal reversed this decision on July 21, 2010, in part because "the conditions for a valid selection patent [do not] constitute an independent basis upon which to attack the validity of a patent."[49] The Court of Appeal held that the '113 patent was both novel and non-obvious and remanded for addressing whether it possessed utility.[50]

The Trial Court revisited the case and on November 10, 2011, it nonsuited Lilly's claims once more.[51] This time it found that the '113 patent lacked utility in failing to meet its promise of "marked superiority" over related compounds.[52] Specifically, the Trial Court Justice explained that,

> If the utility of the invention in the '113 [sic] patent relates merely to a compound with potential antipsychotic properties that might have relatively low [side effects], that utility had been demonstrated by the tests conducted prior to the filing date. However, I cannot accept that the '113's [sic] promise was so small . . . . [B]ased on the wording of the '113 [sic] patent . . . I find that the promise of the patent is that olanzapine treats schizophrenia patients in the clinic in a markedly superior fashion with a better side-effects profile than other known antipsychotics . . . . [W]here a patented compound is claimed to be safe and effective in the treatment of a chronic condition, utility will be demonstrated if the patent discloses studies showing that the patented compound, when administered over a long term, meets that promise . . . .[53]

Again, Lilly appealed the findings to the Court of Appeal.[54] In a decision on September 10, 2012, the Court of Appeal affirmed the Trial Court on the same grounds.[55] In response, Lilly applied for leave to appeal to the Supreme Court, but the application was denied.[56]

C. Litigation of the '735 Patent

Novopharm brought a patent impeachment action to contest the '735 patent's validity, in part based upon utility.[57] On September 14, 2010, the Trial Court invalidated the '735 patent in finding it lacked utility under the promise doctrine.[58] Specifically, the Trial Court explained that,

> In this case the requirement of utility would be met if, at the Canadian filing date of the '735 [p]atent, there was sufficient evidence that atomoxetine was clinically useful in treating some patients with ADHD or, alternatively, that such efficacy could be soundly predicted . . . . [T]he inventors claimed a new use for atomoxetine to effec-

48. *See id.*
49. *See* Eli Lilly Canada Inc. v. Novopharm Ltd., [2010] F.C.A. 197 (Can.).
50. *Id.* ¶ 124.
51. *See* Eli Lilly Canada Inc. v. Novopharm Ltd., [2011] F.C. 1288 (Can.).
52. *Id.* ¶ 262.
53. *Id.* ¶¶ 209–10 (emphasis added).
54. *See generally* Eli Lilly Can. Inc. v. Novopharm Ltd., [2012] F.C.A. 232 (Can.).
55. *Id.* ¶¶ 1–2.
56. *See* Eli Lilly Can. Inc. v. Novopharm Ltd., [2013] CanLII 26762 (Can.).
57. Novopharm Ltd. v. Eli Lilly & Co., [2010] F.C. 915, ¶ 1 (Can.).
58. *Id.* ¶ 122.

tively treat humans with ADHD. What is implicit in this promise is that atomoxetine will work in the longer term.[59]

Lilly appealed the findings to the Court of Appeal.[60] On July 5, 2011, the Court of Appeal affirmed the Trial Court.[61] Although Lilly responded by applying for leave to appeal to the Supreme Court, the application was denied.[62]

D. Post-Invalidation

On November 7, 2012, Lilly filed a notice of intent to arbitrate under NAFTA Chapter 11 against Canada, claiming CND $100 million in damages.[63] The notice focused on the Court of Appeal's invalidation of the '735 patent, which allowed for Strattera generics.[64] Thereafter, Lilly engaged in pre-arbitration negotiations with Canada as mandated by NAFTA.[65] But on June 13, 2013, after concluding that negotiations lacked resolve, Lilly filed a second notice of intent to arbitrate against Canada.[66] The second notice ratcheted up the damages being sought to CND $500 million, to account for lost Zyprex sales since the '113 patent's invalidation.[67]

Then, on September 12, 2013, Lilly filed its precedential arbitration notice against Canada under Chapter 11 for breach of Articles 1110 and 1105, for domestic court application of the promise doctrine.[68] In addition to being the first attempt to contest a Party's patent regime, this case is notable because Lilly is disputing the application of the promise doctrine as applied to the Lilly patents—not the promise doctrine itself.[69] Lilly supported its claims, in part, with Canada violations under NAFTA Chapter 17 and the Patent Cooperation Treaty (PCT).[70]

III. The Viability of Lilly's NAFTA Chapter 11 Claims

A. A Brief Synopsis of NAFTA

The provisions in NAFTA have been legally binding on Canada, the United States, and Mexico since 1994.[71] A bilateral investment treaty, NAFTA was enacted to "create an expanded and secure market for the goods and services produced in their territories."[72]

59. *Id.* ¶¶ 93, 112 (emphasis added).
60. *See generally* Eli Lilly & Co. v. Teva Can. Ltd., [2011] F.C.A. 220 (Can.).
61. *Id.* ¶ 7.
62. *See* Eli Lilly & Co. v. Teva Can. Ltd., [2011] CanLII 79177 (Can.).
63. Notice of Intent to Submit a Claim to Arbitration Under NAFTA Chapter Eleven, Eli Lilly & Co. v. Can., ¶ 108 (Nov. 7, 2013), *available at* http://italaw.com/sites/default/files/case-documents/italaw1172.pdf.
64. *See generally id.*
65. *See* Notice of Arbitration, *supra* note 1, ¶ 19.
66. *See* Notice of Intent to Submit a Claim to Arbitration Under NAFTA Chapter Eleven, Eli Lilly & Co. v. Can. (June 13, 2013), *available at* http://italaw.com/sites/default/files/case-documents/italaw1530.pdf.
67. *See id.* ¶ 119.
68. *See generally* Notice of Arbitration, *supra* note 1.
69. *See* Jishnu, *supra* note 2.
70. *See* Notice of Arbitration, *supra* note 1, ¶¶ 75, 84.
71. *See* North American Free Trade Agreement, U.S.-Can.-Mex., Dec. 17, 1992, 32 I.L.M. 289 (1993) [hereinafter NAFTA].
72. *Id.* pmbl.

Specifically, NAFTA attempts to break down international trade barriers in order to promote existence of beneficial investment opportunities amongst Parties.[73] Also, NAFTA provides for increased intellectual property rights protections and enhanced enforcement mechanisms beyond those available on the national level.[74] Each Party is required to "ensure that all necessary measures are taken" to uphold NAFTA's provisions at all levels of Party government.[75]

Chapter 11, dubbed the "investor-state provision,"[76] provides direct redress against a Party whose "measures adopted or maintained" result in an investor from another Party being treated inequitably.[77] For investor protection, Article 1110 prohibits Parties from "directly or indirectly nationaliz[ing] or expropriat[ing] an investment of an investor of another Party in its territory or take a measure tantamount to" such.[78] An exception to this exists when such nationalization or expropriation is (A) "for a public purpose"; (B) "on a non-discriminatory basis"; (C) "in accordance with due process of law and Article 1105(1)"; and (D) compensated for.[79] Article 1105 establishes minimum standards of treatment for investors within the Parties.[80] Article 1105(1) requires each Party to treat any investments of the other Parties' investors "in accordance with international law, including fair and equitable treatment and full protection and security."[81]

Chapter 17 sets out intellectual property rights protections, including patent rights.[82] Article 1701(1) mandates each Party to provide the other Parties' investors "adequate and effective protection and enforcement of intellectual property rights, while ensuring that measures to enforce intellectual property rights do not themselves become barriers of legitimate trade."[83] Article 1709, concerning patent rights exclusively, mandates in part that Parties "make patents available for inventions . . . provided that such inventions are new, result from an inventive step, and are capable of industrial application."[84] Further, these "patents shall be available and patent rights enjoyable without discrimination."[85] But an exclusion from patentability applies in part "if preventing in its territory the commercial exploitation . . . is necessary to protect [public policy] . . . including to protect human . . . life or heath"[86] or "diagnostic, therapeutic and surgical methods for the treat-

73. *See id.* ("[Each Party] resolved to: . . . CONTRIBUTE to the harmonious development and expansion of world trade and provide a catalyst to broader international cooperation; . . . REDUCE distortions to trade; . . . [and] ENSURE a predictable commercial framework for business planning and investment . . . .").

74. *See id.* ("[Each Party] resolved to: . . . FOSTER creativity and innovation, and promote trade in goods that are the subject of intellectual property rights . . . ."); *see also id.* art. 102(1)(d) (stating that one objective of NAFTA is to "provide adequate and effective protection and enforcement of intellectual property rights in each Party's territory").

75. *See id.* art. 105.

76. Andrew J. Shapren, *NAFTA Chapter 11: A Step Forward in International Trade Law or a Step Backward for Democracy?*, 17 TEMP. INT'L & COMP. L.J. 323, 326 (2003) ("Chapter 11 of NAFTA, the investor-state provision, sets forth the rules governing the treatment and protection of foreign investments . . . .").

77. NAFTA, *supra* note 71, art. 1101(1).

78. *Id.* art. 1110(1).

79. *Id.* art. 1110(1)(a)–(d).

80. *See generally id.* art. 1105.

81. *See id.* art. 1105(1).

82. *See generally id.*, ch. 17.

83. *Id.* art. 1701(1).

84. *Id.* art. 1709(1).

85. *Id.* art. 1709(7).

86. *Id.* art. 1709(2).

ment of humans."[87] Even though the exclusions concern pending patents, Article 1709(8) allows for patent revocation if "grounds exist that would have justified a refusal to grant the patent."[88]

Although NAFTA's principle purpose is to promote and effectuate international commerce, it also applies to social services.[89] NAFTA partially does this by preserving the Parties' "flexibility to safeguard the public welfare."[90] But all investment treaties attempt to "internationalize[ ] the scope of the value judgments made by domestic judges," which inherently limits domestic judge decision-making discretion.[91] NAFTA critics urge, however, that these effects extend even broader—"chill[ing] . . . [legislative] regulation that happens to interfere with investment."[92] In sum, vetting NAFTA's positive impact on business against its positive impact on public interest will reveal "that [NAFTA] favors investor rights over public welfare."[93]

B. Analysis

Both of Lilly's claims will likely succeed in arbitration. NAFTA Article 1139 defines "investment" to include all "property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit."[94] Because "[p]harmaceutical inventions typically involve investment of capital or other resources during the research and development process,"[95] the Lilly patents qualify as "investments" under Chapter 11. With this, Lilly comports as an "investor of a[nother] Party" under the same because it is "an enterprise of [the United States], that . . . has made an investment" in Canada.[96]

Lilly's first claim is expropriation under Article 1110.[97] Although Article 1110 does not specify what measures constitute direct (or indirect) expropriation,[98] scholars have stated

87. *Id.* art. 1709(3)(a).

88. *Id.* art. 1709(8)(a).

89. *See, e.g.*, Eleanor D. Kinney, *Realizing the International Human Right to Health for Non-Citizens in the United States*, Notre Dame J. Int'l Comp. & Hum. Rts. L. 94, 108 (2011), *available at* http://www3.nd.edu/~ndjicl/V1I1/Kinney%20Article.pdf ("NAFTA applies to all economic sectors including social services.").

90. NAFTA, *supra* note 71, pmbl.

91. Andrew J. Walker, *Conflict of Laws Analyses for the Era of Free Trade*, 20 Am. U. Int'l L. Rev. 1147, 1148 (2005), *available at* http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1155&context=auilr.

92. John B. Fowles, *Swords into Plowshares: Softening the Edge of NAFTA's Chapter 11 Regulatory Expropriations Provisions*, 36 Cumb. L. Rev. 83, 84 (2006).

93. *Id.*

94. NAFTA, *supra* note 71, art. 1139.

95. Brook K. Baker, *Corporate Power Unbound: Investor-State Arbitration of IP Monopolies on Medicines–Eli Lilly and the TPP*, Program on Info. Just. & Intell. Prop. Research Paper Series 1, 13 (2013), *available at* http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1038&context=research.

96. *Id.* at 12; *see also* NAFTA, *supra* note 71 art. 1110 ("No Party may directly or indirectly . . . expropriate an investment of an *investor of another Party* . . . .") (emphasis added).

97. *See* Notice of Arbitration, *supra* note 1, ¶¶ 74–79.

98. *See, e.g.*, Brynn Olsen, *International Local Government Law: The Effect of NAFTA Chapter 11 on Local Land Use Planning*, 4 BYU Int'l L. & Mgmt. Rev. 53, 57 (2007), *available at* http://www.law2.byu.edu/ilmr/articles/winter_2007/BYU_ILMR_winter_2007_3_Olsen.pdf ("NAFTA does not explicitly define either 'expropriation' or 'a measure tantamount to . . . expropriation.'").

that at least "openly avowed state takings of property" will qualify.[99] Lilly's case satisfies this standard. Lilly had the patents and enjoyed their privileges for many years before Canada stripped them of their legal and monetary value.[100] At the very least, Lilly's circumstances amount to "a measure tantamount to . . . expropriation."[101] Article 201 defines "measure" to include "any law, regulation, procedure, *requirement*, or practice."[102] This is sufficiently broad to encompass the promise doctrine, which literally is a "requirement" for patent utility.[103] In determining if a requirement netted an equivalent result to expropriation, tribunals frequently inquire into whether Party action substantially deprived a foreign investor of its investment,[104] as is the case here with invalidation of the Lilly patents.

Lilly also raises a minimum standard of treatment claim under Article 1105.[105] Article 1105 does not specify what rises to the "fair and equitable treatment" that Parties must accord to foreign investors.[106] Accordingly, tribunals vary in how fair and equitable treatment should be applied and under which international body of law.[107] Still, the facts are uncontroverted, and discrimination is clear; the effect of the promise doctrine's application nets in invalidation of pharmaceutical patents exclusively and without legal cause.[108] Moreover, its application results in "manifest arbitrariness [and] blatant unfairness,"[109] at least because of the paradoxical effect stemming from patent novelty requirements and mandatory Phase II testing.

Jurisprudence analysis is one method of defining how a tribunal will decide.[110] But the jurisprudence is inconsistent because of the non-binding treatment it is accorded for subsequent determinations.[111] Still, prior jurisprudence holds some degree of credibility and

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99. WILLIAM W. PARK, ARBITRATION OF INTERNATIONAL BUSINESS DISPUTES: STUDIES IN LAW AND PRACTICE 710 (2d ed. 2012), *available at* http://www.law.yale.edu/documents/pdf/sela/Chapter_IV-D-2_Investment_Arbitration.pdf.

100. *See generally* Notice of Arbitration, *supra* note 1.

101. NAFTA, *supra* note 71, art. 1110(1).

102. *Id.* art. 201 (emphasis added).

103. *See* Apotex, Inc. v. Wellcome Found. Ltd., [2002] 4 S.C.R. 153, 155 (Can.).

104. KHAWAR QURESHI QC, MCNAIR CHAMBERS, BILATERAL INVESTMENT TREATIES (BITs): THE ESSENTIALS 1, 8 (Oct. 2008), *available at* http://www.mcnairchambers.com/media/documents/200810/InvestmentTreatyEssentials_.pdf ("Key Test: Whether action of a state deprives investor of the whole or significant part of investment") (emphasis omitted).

105. *See* Notice of Arbitration, *supra* note 1, ¶¶ 80–84.

106. Kara Dougherty, *Methanex v. United States: The Realignment of NAFTA Chapter 11 with Environmental Regulation*, 27 NW J. INT'L L. & BUS. 735, 744 (2007), *available at* http://scholarlycommons.law.northwestern.edu/cgi/viewcontent.cgi?article=1661&context=njilb.

107. *See, e.g.*, Adnan Kagalwalla, *NAFTA Chapter 11 Tribunals and Their Impact on Signatory States: A Parallel Judicial System and Its Many Potential Dangers*, 3 ENTREPRENEURIAL BUS. L. J. 95, 109 (2008), *available at* http://moritzlaw.osu.edu/students/groups/oseblj/files/2013/04/3-6.pdf ("[B]ecause of the lack of precedent in the NAFTA Chapter 11 tribunal system, the decisions [will] appear at odds with each other.").

108. In Azinian v. United Mexican States, the tribunal found that "the Claimants must show either a denial of justice, or a pretence of form to achieve an internationally unlawful end." As will be shown, it is a posture of this note that the promise doctrine will satisfy either of these requirements. Azinian v. United Mexican States, ICSID Case No. ARB(AF)/97/2, Award (Nov. 1, 1999), 14 ICSID Rev.—Foreign Inv. L.J. 68 (1999).

109. Glamis Gold, Ltd. v. United States, Award ¶ 22, NAFTA Ch. 11 Arb. Trib. (June 8, 2009).

110. *See* Kagalwalla, *supra* note 107, at 111.

111. *See id.* at 109.

influence with other tribunals and, thus, can be useful in determining legal boundaries.[112] This note will analyze Lilly's claims against two determinations where the claimant's Article 1110 and 1105 claims each failed, *Azinian v. United Mexican States*[113] and *Glamis Gold Ltd. v. United States*.[114]

In *Azinian*, a Mexican waste collection company filed claims, under Article 1110 and 1105, against Mexico for allowing its domestic courts to annul its work contract with a Mexican city on grounds that it was void or rescindable for non-performance.[115] In finding that the core of the claimant's Article 1110 claim was for "breach of [a] Concession Contract," the tribunal concluded that mere contractual breach is insufficient under NAFTA.[116] The tribunal did note that "[t]he words 'confiscatory,' 'destroy contractual rights as an asset,' or 'repudiation' may serve . . . as acts of expropriation."[117] Further, it determined that a Party cannot be liable "for acting in a manner validated by its courts *unless the courts themselves are disavowed at the international level* . . . . [T]he Claimants must show either a denial of justice, or a pretence of form to achieve an internationally unlawful end."[118] In rejecting the Article 1105 claim, the tribunal determined that "[t]he only conceivably relevant substantive principle of Article 1105 is that a NAFTA investor should not be dealt with in a manner that contravenes international law."[119]

In *Glamis Gold*, a Canadian mining company filed claims, under Article 1110 and 1105, against the United States for allowing a California law that mandated backfilling of open-pit mining operations near Native American sacred sights.[120] For the Article 1110 claim, the tribunal determined that the claimant must be "radically deprived of the economical use and enjoyment of its investments, as if the rights related thereto . . . had ceased to exist."[121] On this, it concluded that the mandatory backfilling did not constitute an Article 1110 violation primarily because the "claimant still formally possessed its mining rights and could exploit mineral resources at a profit," only under modified circumstances.[122] Regarding the claimant's Article 1105 claim, the tribunal decided that Article 1105 should be decided under customary international law.

> [A] violation of the customary international law minimum standard of treatment . . . requires an act that is sufficiently egregious and shocking—a gross denial of justice, manifest arbitrariness, blatant unfairness, a complete lack of due process, evident dis-

112. *See, e.g.*, Alberto R. Salazar V., *NAFTA Chapter 11, Regulatory Expropriation, and Domestic Counter-Advertising Law*, 27 ARIZ. J. INT'L & COMP. L. 31, 50 (2010), *available at* http://www.ajicl.org/AJICL2010/2.27.1Salazar.pdf ("Although the [ ] decisions do not set binding precedents and the principles of stare decisis do not apply, decisions . . . may become influential in narrowing the definition of expropriation and setting out the scope of a government's regulatory power under NAFTA").

113. *See generally* Azinian, ICSID Case No. ARB(AF)/97/2, Award.

114. *See generally Glamis Gold*, Award ¶ 10.

115. *See* Azinian v. United Mexican States, ICSID Case No. ARB(AF)/97/2, Award (Nov. 1, 1999), 14 ICSID Rev.—Foreign Inv. L.J. 68, ¶ 35 (1999).

116. *Id.* ¶ 87.

117. *Id.* ¶ 90.

118. *Id.* ¶ 99 (emphasis added).

119. *Id.* ¶ 92.

120. *See generally* Glamis Gold, Ltd. v. United States, Award ¶ 10, NAFTA Ch. 11 Arb. Trib. (June 8, 2009).

121. *Id.* ¶ 357.

122. *See* Stephen W. Schill, *Glamis Gold, Ltd. v. United States*, 104 AM. J. INT'L L. 253, 255 (2010) (citing *Glamis Gold*, Award ¶ 353 – 536).

> crimination, or a manifest lack of reasons—so as to fall below accepted international standards . . . .[123]

The tribunal did not find that the California law specifically targeted the claimant's investment but instead that it was general applied in both form and effect.[124] More, the California law was found to be rationally related to legitimate government interests, thus not manifestly arbitrary.[125]

Lilly's case diverges from both *Azinian* and *Glamis Gold* on its merits. Lilly's Article 1110 claim is distinct from that in *Azinian* because domestic Canadian courts applied the promise doctrine in a way that amounted to "a denial of justice,"[126] and is "disavowed at the international level."[127] Indeed, the promise doctrine only exists in Canada,[128] and only three other countries have an arguably similar restriction.[129] Further, Lilly's Article 1110 claim is dissimilar from that in *Glamis Gold* because Lilly lost significant monetary and legal privileges when the Lilly patents were invalidated.[130] Today, the Lilly patents have zero significance because they neither protect Lilly's rights to the respective technologies, nor can they be exploited for profit; they have effectively "ceased to exist."[131]

For Article 1105 purposes, both *Azinian* and *Glamis Gold* diverge from Lilly's claim on their merits. Under *Azinian*, Lilly's claim stands; the Canadian courts' application of the promise doctrine "contravenes international law."[132] The promise doctrine has only been used to expropriate from the pharmaceutical industry and has only been applied in Canada.[133] More, Lilly's Article 1105 claim holds merit under *Glamis Gold*. The promise doctrine's application leads to "manifest arbitrariness, blatant unfairness . . . [and] evident discrimination" in form and effect.[134] Zyprexa and Strattera have achieved vast notoriety in Canada,[135] but that is a nonfactor to patent utility; promises must be proven as of the filing date.[136] This is manifestly arbitrary and blatantly unfair because it "establishes an impractical evidentiary burden since it is impossible to predict at the date of filing how

123. *Glamis Gold*, Award ¶ 627.

124. *See* Schill, *supra* note 122, at 257.

125. *See id.*

126. Azinian v. United Mexican States, ICSID Case No. ARB(AF)/97/2, Award (Nov. 1, 1999), 14 ICSID Rev.—Foreign Inv. L.J. 68, ¶ 100 (1999).

127. *Id.* ¶ 97.

128. *See* Livia Aumand, *Court of Appeal Tempers "Promise of the Patent" Doctrine*, GOWLINGS (July 2013), http://www.gowlings.com/KnowledgeCentre/article.asp?pubID=2966 ("The doctrine of the 'promise of the patent' is unique to Canadian patent law.").

129. *See* Rajarshi Banerjee, *The Success of, and Response to, India's Law against Patent Layering*, 54 HARVARD INT'L L.J. 204, 206 (2013), *available at* http://www.harvardilj.org/wp-content/uploads/2013/06/Banerjee-to-Publish.pdf ("[D]eveloping countries that wish to curb patent layering are taking note of India's law, and at least two countries—the Philippines and Argentina—have adopted similar provisions."). R. Banerjee's note discusses § 3(d) of the India Patents (Amendment) Act, an anti-"patent evergreening" measure that adds an additional requirement to patent novelty. *See generally id.*

130. *See* Schill, *supra* note 122, at 255.

131. Glamis Gold, Ltd. v. United States, Award ¶ 357, NAFTA Ch. 11 Arb. Trib. (June 8, 2009).

132. Azinian v. United Mexican States, ICSID Case No. ARB(AF)/97/2, Award (Nov. 1, 1999), 14 ICSID Rev.—Foreign Inv. L.J. 68, ¶ 92 (1999).

133. *See* Aumand, *supra* note 128.

134. *Glamis Gold*, Award ¶ 627.

135. *See* Notice of Arbitration, *supra* note 1, ¶¶ 26–27.

136. *See id.*, ¶ 35.

specifically useful a patent is."[137] It could be argued that the promise doctrine does not discriminate because the "promise" disclosure within the patent is not legally required of by the patentee and it does not exclusively apply to pharmaceutical patents.[138] But "[u]nder Article 1101, the government 'measure' at issue must relate to an appropriate investor or investment" and "tribunals (correctly) focus[ ] on the effects of the measure on the business of the investor or investment."[139] Here, "the effects of the measure" clearly discriminate against pharmaceutical industry investors.[140]

It is worth noting that Articles 1709(2) and (3) should not bar Lilly's claims. Article 1709(2) allows exclusions to "protect human . . . life or heath";[141] thus, Canada would have to concede that the promise doctrine intends to discriminate against pharmaceutical patents. But Lilly is contesting the promise doctrine's application under Canada's current regulatory pharmaceutical framework[142]—utility and novelty are at paradox with the promise doctrine and Phase II testing requirements,[143] rendering it out of sync with international law—and thus will still fail under international law. More, Article 1709(3) only applies to the '735 patent (as "therapeutic . . . method[ ] for the treatment of [ADHD in] humans")[144] because the '113 patent does not disclose methods for treatment.[145] Accordingly, this provision at most should only affect claims related to the '735 patent.

IV. The Far-Reaching Consequences of Lilly's Dispute

NAFTA arbitration determinations only bind the respective parties and only apply to the respective dispute.[146] But even if Lilly's action is dismissed, NAFTA member states (and frankly, member states to any free trade agreement) will likely feel an aftermath of effects for some time. These effects could likely be attributable to major pharmaceutical companies reallocating resources outside of, and reducing expenditures within, Canada, and increased arbitration filings in response to patent invalidation by Canadian courts. Now without question, the pharmaceutical industry is aware of the potential post-patent invalidation redress mechanism that has existed beneath them for over two decades.[147] Now that Chapter 11 has gained notoriety for this purpose, investment treaty Parties are vulnerable "to a slew of investor-state attacks from other drug companies that have had

137. Michelle Wein, *Is it Useful? A Drug Patent Enigma*, THE INNOVATION FILES (Oct. 21, 2013), http://www.innovationfiles.org/is-it-useful-a-drug-patent-enigma/.

138. *See* Aumand, *supra* note 128 ("[T]he promise doctrine holds that *if a patent promises a particular utility*, the patentee will have had to demonstrate or soundly predict that utility by the Canadian filing date.") (emphasis added).

139. Todd Weiler, *NAFTA Chapter 11 Jurisprudence: Coming Along Nicely*, 9 SW. J.L. & TRADE AMERICAS 245, 253 (2003), *available at* http://apps.americanbar.org/intlaw/hubs/programs/Annual0312.01.pdf.

140. *Id.*

141. NAFTA, *supra* note 71, art. 1709(2).

142. *See* Jishnu, *supra* note 2.

143. *See* Lechleiter, *supra* note 42.

144. NAFTA, *supra* note 71, art. 1709(3).

145. *See* CA Patent No. 2,041,113 (filed Apr. 24, 1991).

146. *See* Salazar, *supra* note 112.

147. *See generally* Notice of Arbitration, *supra* note 1.

patents invalidated."[148] A favorable determination for Lilly could have even worse consequences. A windfall for Lilly may push the pharmaceutical industry into "unleash[ing] a wave of challenges to patent decision in other countries which have bilateral investment treaties with the United States or European Union."[149]

Another potential consequence that is considerably more significant is the effect of Lilly's complaint on future international negotiations. Lilly's dispute filing comes at a time when investment treaties are widespread, abundant in quantity, and emerging into existence at roughly one per annum.[150] Indeed, country leaders engaged in treaty negotiations have taken stock of Canada's promise doctrine, as evidenced by emerging treaty provisions.[151] Two such treaties, the Trans-Pacific Partnership (TPP) and the Transatlantic Trade and Investment Partnership/Transatlantic Free Trade Agreement (TTIP/TAFTA), each propose to strengthen intellectual property rights.[152] Although much of what the TTIP/TAFTA entails remains confidential, a draft of the TPP was leaked and provides a baseline for support.[153] Concerning patents exclusively, the TPP proposes to loosen "standards of patentability, to eliminate certain patent exclusions, to extend patent terms to compensate for regulatory delays, to limit required disclosures, to forbid pregrant opposition procedures, and to require data exclusivity and patent-registration linkage"[154]—measures well beyond those in NAFTA.[155] Only time will tell if the final TPP will include a provision to purposefully render Party application of the promise doctrine treaty-incompliant.

V. Conclusion

Although Lilly's arbitration will not occur for several years, it is important to cogitate on its implications today. Currently, the actual impact of Chapter 11 is unrefined; but this is in a constant flux. Even though Lilly's arbitration is only binding on, and directly con-

148. *U.S. Pharmaceutical Corporation Uses NAFTA Foreign Investor Privileges Regime to Attack Canada's Medicine Patent Policy, Demand $100 Million for Denial of a Patent*, PUBLIC CITIZEN (Mar. 2013), https://www.citizen.org/eli-lilly-investor-state-factsheet.

149. Stuart Trew, *Eli Lilly's NAFTA Lawsuit Should Prompt Rethink of Investor 'Rights' Deals*, RABBLE (Sept. 3, 2013), http://rabble.ca/blogs/bloggers/council-canadians/2013/09/eli-lillys-nafta-lawsuit-should-prompt-rethink-investor-rig.

150. *See* Banerjee, *supra* note 129, at 228 ("Since TRIPS came into force in 1995, the United States and the European Union . . . have signed about two dozen free trade agreements . . . .").

151. *See id.* at 231 (discussing that the leaked draft of the TPP includes a provision (Article 8.1) that expressly requires parties thereto to allow for patenting what Section 3(d) of the India Patents (Amendment) Act disallows).

152. *See, e.g., id.*; *see also* Glyn Moody, *EU Mandate for TAFTA Leaked: Includes Investor-State Dispute Resolution for Intellectual Monopolies*, TECHDIRT (May 31, 2013, 12:13 AM) http://www.techdirt.com/articles/20130530/12171523255/ (discussing that the European Parliament passed a resolution regarding TTIP/TAFTA stating that it "should include strong protection of precisely and clearly defined areas of intellectual property rights").

153. For the "Intellectual Property Rights Chapter" of the TPP, see generally Trans-Pacific Partnership, Intellectual Property Rights Chapter, Sept. 2011, *available at* http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf.

154. *See* Baker, *supra* note 95, at 6 n.21.

155. For a comparison of the TPP and NAFTA, see JIMMY H. KOO, TABLE COMPARING THE PATENT LAW REGIMES: TPP VS. CANADA, MEXICO, AND NAFTA, *available at* http://infojustice.org/wp-content/uploads/2012/08/Koo-TPP-NAFTA-Canada-Mexico-version-08152012.pdf (last visited Feb. 5, 2014).

cerns, Lilly and the Canadian sovereign, it is monumental in effect. Not only does this scenario affect the everyday person and his or her ability to access critical medicines, but also it affects global frameworks that may be coming sooner than later. Indeed, as evidenced by the draft TTP provisions and beyond,[156] Lilly's dispute may have already left a mark on the landscape of investment treaty negotiations that may indefinitely carry forward.

156. *See, e.g.*, Banerjee, *supra* note 129, at 231 (discussing that the leaked draft of the TPP includes a provision (Article 8.1) that expressly requires parties thereto to allow for patenting what Section 3(d) of the India Patents (Amendment) Act disallows).